VALUE IN HEALTH 16 (2013) A323–A636

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/jval

ABSTRACTS

ISPOR 16TH ANNUAL EUROPEAN CONGRESS RESEARCH ABSTRACTS

RESEARCH PODIUM PRESENTATIONS – SESSION I
HEALTH CARE EXPENDITURE OR REIMBURSEMENT STUDIES – BIOLOGICS

BI1
ADHERENCE AND RESOURCE USE AMONG PATIENTS TREATED WITH BIOLOGICS. FINDINGS FROM THE BEETLE STUDY (BIOLOGICAL DRUGS: EVALUATION OF ECONOMICS, TREATMENTS, AND LABELING IN REAL-WORLD SETTING)

Degli Esposti L, Sangiorgi D, Buda S
CliCon Srl, Ravenna, Italy

OBJECTIVES: Systemic administration of anti-TNF alpha leads to an anti-inflammatory and joint protective effect in pathologies such as rheumatoid arthritis, psoriasis, Crohn's disease. The aim of this study was to assess adherence to therapy and stay on treatment (no switches or interruptions) of patients treated with biologics according to therapeutic indication and to calculate health care resources consumption (drugs, outpatient services, hospitalizations). **METHODS:** An observational retrospective cohort analysis based on 5 Local Health Units administrative databases was conducted. Patients who filled at least one prescription for anti-TNF alpha between January 1, 2009-December 31, 2011 were included. Patients were followed-up for one year. Patients were defined as adherent if they had >80% of follow up period covered by drugs dispensation. **RESULTS:** A total of 1219 patients were analyzed, 47% male, age 49.6±14.6. Patients affected by rheumatoid arthritis were 36%, psoriasis 31%, Crohn's disease 10%, psoriatic arthritis 7%, ulcerative colitis 3%, ankylosing spondylitis 3%, diagnosis not available 11%; 420 (34%) were treated with Adalimumab, 615 (50%) Etanercept, 184 (15%) Infliximab. Among the 94% of patients who did not switch, patients treated with Infliximab seemed to have the highest rate of adherent patients across all indications: 51%, vs. 27% Etanercept and 23% Adalimumab; at the multivariable logistic regression model, Infliximab resulted a protective predictor of non adherence for all indications (OR ranged from 0.08 to 0.43). For patients who started a first-line biological drug, stay on treatment was 73% for Infliximab, 67% Etanercept, 64% Adalimumab. The mean annual expenditure for each patient in analysis was €11,120; in particular, non-pharmacological expenditure was €988 for adherent and €1,255 for non-adherent patients; at the multivariable generalized linear model, Infliximab was associated with the lowest cost for all indications. **CONCLUSIONS:** Patients treated with Infliximab were associated to higher adherence and stay on treatment and lower costs, as compared to Adalimumab and Etanercept.

BI2
WHAT ARE THE KEY DRIVERS OF REIMBURSEMENT FOR BIOSIMILARS? AN EXAMINATION OF REIMBURSEMENT PROCESSES AND RECOMMENDATIONS ACROSS NINE COUNTRIES

de Silva SU, Smith TA, Bending MW
Mapi, London, UK

OBJECTIVES: Biosimilars are biotherapeutic products that are similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product. The first biosimilar (Omnitrope) received EU regulatory approval in 2006; since then, 14 biosimilars have received marketing authorisation. This study examined the differences in the approaches to reimbursement of biosimilars in countries using HTA to inform decision-making. **METHODS:** Four biosimilar medicines were selected to provide sufficient documentation in seven European countries, South Korea and Australia. Regulatory approval and HTA reimbursement decision documents were identified and a qualitative analysis of the processes, recommendations by indication, evidence and key decision drivers was undertaken to explain differences in recommendations across countries. **RESULTS:** Twenty-one different indications were appraised; 90% of appraisals were 'recommended', 9% 'recommended with restrictions', and 1% were 'not recommended'. The Netherlands and Germany accepted 'clinical comparability' to the originator as sufficient evidence for automatic reimbursement. Sweden and France were the only countries to appraise and to recommend for all indications. Scotland and Wales recommended all biosimilars but restricted indications in some cases. Agencies accepted the notion of clinical comparability and extrapolation across indications when appraising the evidence. A cost-minimisation analysis and budget impact analysis were key economic decision drivers. A full cost-effectiveness analysis was only requested by NICE. Other factors influential in recommending reimbursement were: lobbying, dual reimbursement processes, and other reimbursement mechanisms. **CONCLUSIONS:** As the market for biosimilars continues to grow, it is imperative that specific HTA reimbursement processes are developed for assessing biosimilars. This includes further research on how different drug classes should be considered; especially pertinent due to the increase in biosimilars for monoclonal antibody-based drugs, which differ from the product classes (erythropoietin, white blood cell stimulators, growth hormone and insulins) currently dominating the market.

BI3
DIFFERENCES IN APPROACH TO BIOSIMILARS: NICE VERSUS SMC RECOMMENDATIONS

Izmirlieva M, Ando G
IHS, London, UK

OBJECTIVES: Several biosimilar products have been approved for marketing in the European Union, but their market penetration remains slow. Lack of clear reimbursement guidance could be one of the reasons for this slow penetration. This study examines how many, if any, biosimilar products have been assessed in the UK by NICE and by the SMC and to what extent recommendations by the two HTA organisations are consistent. **METHODS:** Secondary research was conducted, including a review of all NICE and SMC final guidance and of guidance in progress by NICE to compare the HTA process outcome and issues raised by the two HTA agencies. **RESULTS:** NICE has issued only one final guidance for a biosimilar product (Omnitrope) and has another guidance in progress (for epoetin including biosimilars). The SMC has issued guidance for 4 biosimilar versions of filgrastim (Ratiograstim, TevaGrastim, Zarzio and Nivestim), 2 biosimilar versions of epoetin (Binocrit and Retacrit) and 1 version of somatropin (Omnitrope). All SMC guidance for biosimilars issued to date has been positive. The NICE guidance for Omnitrope is positive despite some reservations about the economic model. **CONCLUSIONS:** Considering the limited overlap between NICE and SMC decisions (only one drug - Omnitrope - was considered by both agencies), it is difficult to assess consistency in the SMC approach compared to NICE's approach at this stage. Based on the biosimilars HTA guidance by NICE and the SMC to date, a cost-minimisation analysis may be acceptable for biosimilars even if such an approach - in the absence of a full cost-effectiveness model - might be rejected for an originator product. Both HTA agencies recommend that prescribing for biosimilars should be by brand name to avoid automatic substitution in the pharmacy.

BI4
IMPACT OF EXCLUSIVE HOSPITAL DISTRIBUTION OF BIOSIMILAR ON DRUG HEALTH CARE BUDGET

Rémuzat C[1], Vataire AL[2], Cetinsoy L[2], Aballea S[1], Toumi M[3]
[1]*Creativ-Ceutical, Paris, France,* [2]*Creativ-Ceutical, PARIS, France,* [3]*University Claude Bernard Lyon 1, Lyon, France*

OBJECTIVES: There is an increased trend in shifting biologics distribution to exclusive hospital pharmacy channel. Although it looks obvious that such process will generate savings through tenders at regional or national level such policy consequences were not clearly quantified. We used a model developed for EU commission to assess the consequences of such policies on biosimilars for selected EU countries (model developed for the European Commission for the project"EU Pharmaceutical expenditure forecast" http://ec.europa.eu/health/healthcare/key_documents/index.en.htm). **METHODS:** We built a model to assess policy scenarios impact on pharmaceuticals reference forecast for seven EU Member States (France, the UK, Germany, Poland, Portugal, Greece and Hungary). We tested the impact of shifting biosimilar distribution to hospital channel on pharmaceutical industry revenue, Health insurers budget and society cost. **RESULTS:** For the period 2012-2016 the savings of biosimilars (based in million Euros) for Health insurance will be for: UK 2,023; GE 1,127; FR 1,634; PL 200; GR 19; PO 272; HU 29. The extra savings by shifting of the biosimilars distribution to exclusive hospital pharmacy will be: for UK 353; GE 3,392; FR 1,684; PL 37; GR 206; PO 65; HU 176. The difference is relatively small for UK, although significant. However, it is considerable for Germany and France (around 3 and 2 time original saving). Similar figures (revenue loss) are seen for pharmaceutical companies. **CONCLUSIONS:** Although the impact of such policy varies from one country to one another based on initial proportion of biosimilar distributed through hospital and level of discount over branded products, this policy appears to have a substantial impact on drug expenditures and might contribute to sustainability of health insurance in EU countries. Germany and France might benefit dramatically from such policy.

CANCER OUTCOMES RESEARCH STUDIES

CA1
RESPONSIVENESS OF THE EQ-5D IN ONCOLOGY: A META-ANALYSIS

Smith AB[1], Cocks K[1], Taylor M[2], Parry D[3]
[1]*University of York, York, UK,* [2]*York Health Economics Consortium, York, UK,* [3]*AstraZeneca UK, Macclesfield, UK*

OBJECTIVES: The EQ-5D is often employed in clinical trials to derive quality-adjusted life years for cost-utility analyses, and in comparisons of health-related quality of life across conditions. However, there are concerns that the EQ-5D is less